Exhibit B

REQUEST FOR ADMISSION NO. 1:

YOU believe there is REASONABLE EVIDENCE OF A CAUSAL ASSOCIATION for every "serious side effect" identified in the Medication Guide for BYETTA.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Request for Admission as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information not related to pancreatic cancer. Information regarding events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. See 8/14/2014 Order at 2:12-19 (defining discovery on preemption issue as question of "what the FDA had or did not have before it on the use of incretin-mimetic therapies and the causal association with pancreatic cancer") (emphasis added); 3/25/2014 Order at 3:6-7 (limiting discovery on general causation issue to that of "the link between the Defendants' pharmaceuticals and pancreatic cancer") (emphasis added).

Subject to and without waiving the foregoing objections, Amylin responds as follows: Pancreatic cancer is not listed as a "serious side effect" in the Medication Guide for Byetta®. Amylin denies that it believes there is reasonable evidence of a causal association between Byetta® and pancreatic cancer.

ELI LILLY'S RESPONSE:

Lilly objects to this request to the extent that it seeks information related to any event other than pancreatic cancer as beyond the scope of preemption or general causation discovery defined in the Order Following August 14, 2014 Case Management Conference (Dkt. 567). Lilly states that pancreatic cancer is not listed as a serious side effect in the Medication Guide for Byetta. Lilly denies that it believes there is reasonable evidence of a causal association between Byetta and pancreatic cancer.

MERCK'S RESPONSE:

Merck objects to this Request for Admission to the extent it seeks information of any event other than pancreatic cancer. Merck states that pancreatic cancer is not listed as a serious side effect in the Medication Guide for JANUVIA® or JANUMET®. Merck denies that it believes there is reasonable evidence of a causal association between JANUVIA® or JANUMET® and pancreatic cancer.

NOVO'S RESPONSE:

NNI objects to this Request to the extent it seeks information unrelated to pancreatic cancer. NNI states that pancreatic cancer is not identified as a "serious side effect" in the Medication Guide for Victoza®. NNI denies that there is reasonable evidence of a causal association between Victoza® and pancreatic cancer.

REQUEST FOR ADMISSION NO. 2:

YOU do not believe there is REASONABLE EVIDENCE OF A CAUSAL ASSOCIATION for every "serious side effect" identified in the Medication Guide for BYETTA.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Request for Admission as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information not related to pancreatic cancer. Information regarding events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. See 8/14/2014 Order at 2:12-19 (defining discovery on preemption issue as question of "what the FDA had or did not have before it on the use of incretin-mimetic therapies and the causal association with pancreatic cancer") (emphasis added); 3/25/2014 Order at 3:6-7 (limiting discovery on general causation issue to that of "the link between the Defendants' pharmaceuticals and pancreatic cancer") (emphasis added).

Subject to and without waiving the foregoing objections, Amylin responds as follows: Pancreatic cancer is not listed as a serious side effect in the Medication Guide for Byetta®. Amylin admits that it does not believe there is reasonable evidence of a causal association between Byetta® and pancreatic cancer.

ELI LILLY'S RESPONSE:

Lilly objects to this request to the extent that it seeks information related to any event other than pancreatic cancer as beyond the scope of preemption or general causation discovery defined in the Order Following August 14, 2014 Case Management Conference (Dkt. 567). Lilly states that pancreatic cancer is not listed as a serious side effect in the Medication Guide for Byetta. Lilly admits that it does not believe there is reasonable evidence of a causal association between Byetta and pancreatic cancer.

MERCK'S RESPONSE:

Merck objects to this Request for Admission to the extent it seeks information of any event other than pancreatic cancer. Merck states that pancreatic cancer is not listed as a serious side effect in the Medication Guide for JANUVIA® or JANUMET®. Merck admits that it does not believe there is reasonable evidence of a causal association between JANUVIA® or JANUMET® and pancreatic cancer.

NOVO'S RESPONSE:

NNI objects to this Request to the extent it seeks information unrelated to pancreatic cancer. NNI states that pancreatic cancer is not identified as a "serious side effect" in the Medication Guide for Victoza®. NNI admits that there is not a reasonable evidence of a causal association between Victoza® and pancreatic cancer.

REQUEST FOR ADMISSION NO. 3:

YOU believe there is REASONABLE EVIDENCE OF A CAUSAL ASSOCIATION for every medical condition identified in the Highlights, Warnings and Precautions, Adverse Reactions, Nonclinical Toxicology, Clinical Studies, Patient Counseling Information, and Medication Guide for BYETTA.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Request for Admission as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information not related to pancreatic cancer. Information regarding events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. See 8/14/2014 Order at 2:12-19 (defining discovery on preemption issue as question of "what the FDA had or did not have before it on the use of incretin-mimetic therapies and the causal association with pancreatic cancer") (emphasis added); 3/25/2014 Order at 3:6-7 (limiting discovery on general causation issue to that of "the link between the Defendants' pharmaceuticals and pancreatic cancer") (emphasis added). Subject to and without waiving the foregoing objections, Amylin responds as follows: Pancreatic cancer has never been included in the Highlights, Warnings and Precautions, Adverse Reactions, Nonclinical Toxicology, Clinical Studies, or Patient Counseling Information sections, or in the Medication Guide for Byetta®. Amylin denies that it believes there is reasonable evidence of a causal association between Byetta® and pancreatic cancer.

ELI LILLY'S RESPONSE:

Lilly objects to this request to the extent that it seeks information related to any event other than pancreatic cancer as beyond the scope of preemption or general causation discovery defined in the Order Following August 14, 2014 Case Management Conference (Dkt. 567). Lilly states that pancreatic cancer is not listed in the Highlights, Warnings and Precautions, Adverse Reactions, Nonclinical Toxicology, Clinical Studies, Patient Counseling Information, or Medication Guide for Byetta. Lilly denies that it believes there is reasonable evidence of a causal association between Byetta and pancreatic cancer.

MERCK'S RESPONSE:

Merck objects to this Request for Admission to the extent it seeks information of any event other than pancreatic cancer. Merck states that pancreatic cancer is not listed as a Highlights, Warnings and Precautions, Adverse Reactions, Nonclinical Toxicology, Clinical Studies, Patient Counseling Information, and

Medication Guide for JANUVIA® or JANUMET®. Merck denies that it believes there is reasonable evidence of a causal association between JANUVIA® or JANUMET® and pancreatic cancer.

NOVO'S RESPONSE:

NNI objects to this Request to the extent it seeks information unrelated to pancreatic cancer. NNI states that pancreatic cancer is not identified in the Highlights, Warnings and Precautions, Adverse Reactions, Nonclinical Toxicology, Clinical Studies, Patient Counseling Information, or Medication Guide for Victoza®. NNI denies that there is reasonable evidence of a causal association between Victoza® and pancreatic cancer.

REQUEST FOR ADMISSION NO. 4:

YOU do not believe there is REASONABLE EVIDENCE OF A CAUSAL ASSOCIATION for every medical condition identified in the Highlights, Warnings and Precautions, Adverse Reactions, Nonclinical Toxicology, Clinical Studies, Patient Counseling Information, and Medication Guide for BYETTA.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Request for Admission as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information not related to pancreatic cancer. Information regarding events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. See 8/14/2014 Order at 2:12-19 (defining discovery on preemption issue as question of "what the FDA had or did not have before it on the use of incretin-mimetic therapies and the causal association with pancreatic cancer") (emphasis added); 3/25/2014 Order at 3:6-7 (limiting discovery on general causation issue to that of "the link between the Defendants' pharmaceuticals and pancreatic cancer") (emphasis added).

Subject to and without waiving the foregoing objections, Amylin responds as follows: Pancreatic cancer has never been included in the Highlights, Warnings and Precautions, Adverse Reactions, Nonclinical Toxicology, Clinical Studies, or Patient Counseling Information sections, or in the Medication Guide for Byetta®. Amylin admits that it does not believe there is reasonable evidence of a causal association between Byetta® and pancreatic cancer.

ELI LILLY'S RESPONSE:

Lilly objects to this request to the extent that it seeks information related to any event other than pancreatic cancer as beyond the scope of preemption or general causation discovery defined in the Order Following August 14, 2014 Case Management Conference (Dkt. 567). Lilly states that pancreatic cancer is not listed in the Highlights, Warnings and Precautions, Adverse Reactions, Nonclinical Toxicology, Clinical Studies, Patient Counseling Information, or Medication Guide for Byetta. Lilly admits that it does not believe there is reasonable evidence of a causal association between Byetta and pancreatic cancer.

MERCK'S RESPONSE:

Merck objects to this Request for Admission to the extent it seeks information of any event other than pancreatic cancer. Merck states that pancreatic cancer is not listed as a Highlights, Warnings and Precautions, Adverse Reactions, Nonclinical Toxicology, Clinical Studies, Patient Counseling Information, and

Medication Guide for JANUVIA® or JANUMET®. Merck admits that it does not believe there is reasonable evidence of a causal association between JANUVIA® or JANUMET® and pancreatic cancer.

NOVO'S RESPONSE:

NNI objects to this Request to the extent it seeks information unrelated to pancreatic cancer. NNI states that pancreatic cancer is not identified in the Highlights, Warnings and Precautions, Adverse Reactions, Nonclinical Toxicology, Clinical Studies, Patient Counseling Information, or Medication Guide for Victoza®. NNI admits that there is not reasonable evidence of a causal association between Victoza® and pancreatic cancer.

REQUEST FOR ADMISSION NO. 5:

YOU believe there is REASONABLE EVIDENCE OF A CAUSAL ASSOCIATION for every "serious side effect" identified in the Medication Guide for every branded prescription drug YOU sell.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Request for Admission as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information not related to Byetta® and pancreatic cancer. Information regarding drugs other than Byetta® and events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. See 8/14/2014 Order at 2:12-19 (defining discovery on preemption issue as question of "what the FDA had or did not have before it on the use of incretin-mimetic therapies and the causal association with pancreatic cancer") (emphasis added); 3/25/2014 Order at 3:6-7 (limiting discovery on general causation issue to that of "the link between the Defendants' pharmaceuticals and pancreatic cancer") (emphasis added).

Subject to and without waiving the foregoing objections, Amylin responds as follows: Pancreatic cancer is not listed as a serious side effect in the Medication Guide for Byetta®. Amylin denies that it believes there is reasonable evidence of a causal association between Byetta® and pancreatic cancer.

ELI LILLY'S RESPONSE:

Lilly objects to this request to the extent that it seeks information related to any drugs other than Byetta and any event other than pancreatic cancer as beyond the scope of preemption or general causation discovery defined in the Order Following August 14, 2014 Case Management Conference (Dkt. 567). Lilly states that pancreatic cancer is not identified as a "serious side effect" in the Medication Guide for Byetta. Lilly denies that it believes there is reasonable evidence of a causal association between Byetta and pancreatic cancer.

MERCK'S RESPONSE:

Merck objects to this Request for Admission to the extent it seeks information on drugs other than JANUVIA® or JANUMET® and of any event other than pancreatic cancer. Merck states that pancreatic cancer is not listed as a serious side effect in the Medication Guide for JANUVIA® or JANUMET®. Merck denies that it believes there is reasonable evidence of a causal association between JANUVIA® or JANUMET® and pancreatic cancer.

NOVO'S RESPONSE:

NNI objects to this Request to the extent it seeks information regarding products other than Victoza® and information unrelated to pancreatic cancer. NNI states that pancreatic cancer is not identified as a "serious side effect" in the Medication Guide for Victoza®. NNI denies that there is reasonable evidence of a causal association between Victoza® and pancreatic cancer.

REQUEST FOR ADMISSION NO. 6:

YOU do not believe there is REASONABLE EVIDENCE OF A CAUSAL ASSOCIATION for every "serious side effect" identified in the Medication Guide for every branded prescription drug YOU sell.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Request for Admission as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information not related to Byetta® and pancreatic cancer. Information regarding drugs other than Byetta® and events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. See 8/14/2014 Order at 2:12-19 (defining discovery on preemption issue as question of "what the FDA had or did not have before it on the use of incretin-mimetic therapies and the causal association with pancreatic cancer") (emphasis added); 3/25/2014 Order at 3:6-7 (limiting discovery on general causation issue to that of "the link between the Defendants' pharmaceuticals and pancreatic cancer") (emphasis added).

Subject to and without waiving the foregoing objections, Amylin responds as follows: Pancreatic cancer is not listed as a serious side effect in the Medication Guide for Byetta®. Amylin admits that it does not believe there is reasonable evidence of a causal association between Byetta® and pancreatic cancer.

ELI LILLY'S RESPONSE:

Lilly objects to the extent that it seeks information related to any drugs other than Byetta and any event other than pancreatic cancer as beyond the scope of preemption or general causation discovery defined in the Order Following August 14, 2014 Case Management Conference (Dkt. 567). Lilly states that pancreatic cancer is not identified as a "serious side effect" in the Medication Guide for Byetta. Lilly admits that it does not believe there is reasonable evidence of a causal association between Byetta and pancreatic cancer.

MERCK'S RESPONSE:

Merck objects to this Request for Admission to the extent it seeks information on drugs other than JANUVIA® or JANUMET® and of any event other than pancreatic cancer. Merck states that pancreatic cancer is not listed as a serious side effect in the Medication Guide for JANUVIA® or JANUMET®. Merck admits that it does not believe there is reasonable evidence of a causal association between JANUVIA® or JANUMET® and pancreatic cancer.

NOVO'S RESPONSE:

NNI objects to this Request to the extent it seeks information regarding products other than Victoza® and information unrelated to pancreatic cancer. NNI states that pancreatic cancer is not identified as a "serious side effect" in the Medication Guide for Victoza®. NNI admits that there is not reasonable evidence of a causal association between Victoza® and pancreatic cancer.

REQUEST FOR ADMISSION NO. 7:

YOU believe there is REASONABLE EVIDENCE OF A CAUSAL ASSOCIATION for every medical condition identified in the Highlights, Warnings and Precautions, Adverse Reactions, Nonclinical Toxicology Clinical Studies, Patient Counseling Information, and Medication Guide for every branded prescription drug YOU sell.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Request for Admission as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information not related to Byetta® and pancreatic cancer. Information regarding drugs other than Byetta® and events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. See 8/14/2014 Order at 2:12-19 (defining discovery on preemption issue as question of "what the FDA had or did not have before it on the use of incretin-mimetic therapies and the causal association with pancreatic cancer") (emphasis added); 3/25/2014 Order at 3:6-7 (limiting discovery on general causation issue to that of "the link between the Defendants' pharmaceuticals and pancreatic cancer") (emphasis added).

Subject to and without waiving the foregoing objections, Amylin responds as follows: Pancreatic cancer has never been included in the Highlights, Warnings and Precautions, Adverse Reactions, Nonclinical Toxicology, Clinical Studies, or Patient Counseling Information sections, or in the Medication Guide for Byetta®. Amylin denies that it believes there is reasonable evidence of a causal association between Byetta® and pancreatic cancer.

ELI LILLY'S RESPONSE:

Lilly objects to the extent that it seeks information related to any drugs other than Byetta and any event other than pancreatic cancer. Lilly further objects to this request as beyond the scope of preemption or general causation discovery defined in the Order Following August 14, 2014 Case Management Conference (Dkt. 567). Lilly states that pancreatic cancer is not identified in the Highlights, Warnings and Precautions, Adverse Reactions, Nonclinical Toxicology Clinical Studies, Patient Counseling Information, or Medication Guide for Byetta. Lilly denies that it believes there is reasonable evidence of a causal association between Byetta and pancreatic cancer.

MERCK'S RESPONSE:

Merck objects to this Request for Admission to the extent it seeks information on drugs other than JANUVIA® or JANUMET® and of any event other than pancreatic cancer. Merck states that pancreatic cancer is not listed as a Highlights, Warnings and Precautions, Adverse Reactions, Nonclinical Toxicology, Clinical Studies, Patient Counseling Information, and Medication Guide for JANUVIA® or JANUMET®. Merck denies that it believes there is reasonable evidence of a causal association between JANUVIA® or JANUMET® and pancreatic cancer.

NOVO'S RESPONSE:

NNI objects to this Request to the extent it seeks information regarding products other than Victoza® and information unrelated to pancreatic cancer. NNI states that pancreatic cancer is not identified in the Highlights, Warnings and Precautions, Adverse Reactions, Nonclinical Toxicology, Clinical Studies, Patient Counseling Information, or Medication Guide for Victoza®. NNI denies that there is reasonable evidence of a causal association between Victoza® and pancreatic cancer.

REQUEST FOR ADMISSION NO. 8:

YOU do not believe there is REASONABLE EVIDENCE OF A CAUSAL ASSOCIATION for every medical condition identified in the Highlights, Warnings and Precautions, Adverse Reactions, Nonclinical Toxicology, Clinical Studies, Patient Counseling Information, and Medication Guide for every branded prescription drug YOU sell.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Request for Admission as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information not related to Byetta® and pancreatic cancer. Information regarding drugs other than Byetta® and events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. See 8/14/2014 Order at 2:12-19 (defining discovery on preemption issue as question of "what the FDA had or did not have before it on the use of incretin-mimetic therapies and the causal association with pancreatic cancer") (emphasis added); 3/25/2014 Order at 3:6-7 (limiting discovery on general causation issue to that of "the link between the Defendants' pharmaceuticals and pancreatic cancer") (emphasis added).

Subject to and without waiving the foregoing objections, Amylin responds as follows: Pancreatic cancer has never been included in the Highlights, Warnings and Precautions, Adverse Reactions, Nonclinical Toxicology, Clinical Studies, or Patient Counseling Information sections, or in the Medication Guide for Byetta®. Amylin admits that it does not believe there is reasonable evidence of a causal association between Byetta® and pancreatic cancer.

ELI LILLY'S RESPONSE:

Lilly objects to the extent that it seeks information related to any drugs other than Byetta and any event other than pancreatic cancer. Lilly further objects to this request as beyond the scope of preemption or general causation discovery defined in the Order Following August 14, 2014 Case Management Conference (Dkt. 567). Lilly states that pancreatic cancer is not identified in the Highlights, Warnings and Precautions, Adverse Reactions, Nonclinical Toxicology Clinical Studies, Patient Counseling Information, or Medication Guide for Byetta. Lilly admits that it does not believe there is reasonable evidence of a causal association between Byetta and pancreatic cancer.

MERCK'S RESPONSE:

Merck objects to this Request for Admission to the extent it seeks information on drugs other than JANUVIA® or JANUMET® and of any event other than pancreatic cancer. Merck states that pancreatic cancer is not listed as a Highlights, Warnings and Precautions, Adverse Reactions, Nonclinical Toxicology, Clinical Studies, Patient Counseling Information, and Medication Guide for JANUVIA® or JANUMET®. Merck admits that it does not believe there is reasonable evidence of a causal association between JANUVIA® or JANUMET® and pancreatic cancer.

NOVO'S RESPONSE:

NNI objects to this Request to the extent it seeks information regarding products other than Victoza®. NNI further objects to this Request to the extent it seeks information unrelated to pancreatic cancer. NNI states that pancreatic cancer is not identified in the Highlights, Warnings and Precautions, Adverse Reactions, Nonclinical Toxicology, Clinical Studies, Patient Counseling Information, or Medication Guide for Victoza®. NNI admits that there is not reasonable evidence of a causal association between Victoza® and pancreatic cancer.

REQUEST FOR ADMISSION NO. 9:

To the best of YOUR knowledge, the FDA has never allowed a branded prescription drug to reference a medical condition for which there is no REASONABLE EVIDENCE OF A CAUSAL ASSOCIATION.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Request for Admission as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information not related to Byetta® and pancreatic cancer. Information regarding drugs other than Byetta® and events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. See 8/14/2014 Order at 2:12-19 (defining discovery on preemption issue as question of "what the FDA had or did not have before it on the use of incretin-mimetic therapies and the causal association with pancreatic cancer") (emphasis added); 3/25/2014 Order at 3:6-7 (limiting discovery on general causation issue to that of "the link between the Defendants' pharmaceuticals and pancreatic cancer") Subject to and without waiving the foregoing objections, Amylin responds as follows: Byetta® does not reference pancreatic cancer. Amylin admits that there is no reasonable evidence of a causal association between Byetta® and pancreatic cancer.

ELI LILLY'S RESPONSE:

Lilly objects to this request to the extent that it seeks information on drugs other than Byetta and any event other than pancreatic cancer as beyond the scope of preemption or general causation discovery defined in the Order Following August 14, 2014 Case Management Conference (Dkt. 567). Lilly states that the package insert for Byetta does not reference pancreatic cancer. Lilly admits that the FDA does not believe there is reasonable evidence of a causal association between Byetta and pancreatic cancer.

MERCK'S RESPONSE:

Merck objects to this Request for Admission to the extent it seeks information on drugs other than JANUVIA® or JANUMET® and of any event other than pancreatic cancer. Merck states that neither JANUVIA® nor JANUMET® reference pancreatic cancer. Merck admits that the FDA does not believe there is reasonable evidence of a causal association between JANUVIA® or JANUMET® and pancreatic cancer.

NOVO'S RESPONSE:

NNI objects to this Request as overly broad and unduly burdensome. NNI further objects to this Request to the extent the information is outside the custody and control of NNI. NNI lacks sufficient information to admit or deny that the FDA has never allowed any prescription drug from any manufacturer to reference a medical condition for which there is no reasonable evidence of a causal association.

REQUEST FOR ADMISSION NO. 10:
There is REASONABLE EVIDENCE OF A CAUSAL ASSOCIATION between BYETTA use and pancreatitis.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Request for Admission as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information not related to pancreatic cancer. Information regarding events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. See 8/14/2014 Order at 2:12-19 (defining discovery on preemption issue as question of "what the FDA had or did not have before it on the use of incretin-mimetic therapies and the causal association with pancreatic cancer") (emphasis added); 3/25/2014 Order at 3:6-7 (limiting discovery on general causation issue to that of "the link between the Defendants' pharmaceuticals and pancreatic cancer") (emphasis added).

Subject to and without waiving the foregoing objections, Amylin responds as follows: Amylin denies that there is reasonable evidence of a causal association between Byetta® and pancreatic cancer.

ELI LILLY'S RESPONSE:

Lilly objects to this request to the extent that it seeks information on any event other than pancreatic cancer as beyond the scope of preemption or general causation discovery defined in the Order Following August 14, 2014 Case Management Conference (Dkt. 567). Lilly denies that there is reasonable evidence of a causal association between Byetta and pancreatic cancer.

MERCK'S RESPONSE:

Merck objects to this Request for Admission to the extent it seeks information of any event other than pancreatic cancer. Merck denies that there is reasonable evidence of a causal association between JANUVIA® or JANUMET® and pancreatic cancer.

NOVO'S RESPONSE:

NNI objects to this Request to the extent it seeks information unrelated to pancreatic cancer. NNI denies that there is reasonable evidence of a causal association between Victoza® and pancreatic cancer.

REQUEST FOR ADMISSION NO. 11:

There is no REASONABLE EVIDENCE OF A CAUSAL ASSOCIATION between BYETTA use and pancreatitis.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Request for Admission as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information not related to pancreatic cancer. Information regarding events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. See 8/14/2014 Order at 2:12-19 (defining discovery on preemption issue as question of "what the FDA had or did not have before it on the use of incretin-mimetic therapies and the causal association with pancreatic cancer") (emphasis added); 3/25/2014 Order at 3:6-7 (limiting discovery on general causation issue to that of "the link between the Defendants' pharmaceuticals and pancreatic cancer") (emphasis added).

Subject to and without waiving the foregoing objections, Amylin responds as follows: Amylin admits that there is no reasonable evidence of a causal association between Byetta® and pancreatic cancer.

ELI LILLY'S RESPONSE:

Lilly objects to this request to the extent that it seeks information on any event other than pancreatic cancer as beyond the scope of preemption or general causation discovery defined in the Order Following August 14, 2014 Case Management Conference (Dkt. 567). Lilly admits that there is no reasonable evidence of a causal association between Byetta and pancreatic cancer.

MERCK'S RESPONSE:

Merck objects to this Request for Admission to the extent it seeks information of any event other than pancreatic cancer. Merck admits that there is no reasonable evidence of a causal association between JANUVIA® or JANUMET® and pancreatic cancer.

NOVO'S RESPONSE:

NNI objects to this Request to the extent it seeks information unrelated to pancreatic cancer. NNI admits that there is no reasonable evidence of a causal association between Victoza® and pancreatic cancer.

REQUEST FOR ADMISSION NO. 30:

YOU are in discussions with the FDA about adding a warning for all cancers to the label for BYETTA.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Request for Admission as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information not related to pancreatic cancer. Information regarding events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. See 8/14/2014 Order at 2:12-19 (defining discovery on preemption issue as question of "what the FDA had or did not have before it on the use of incretin-mimetic therapies and the causal association with pancreatic cancer") (emphasis added); 3/25/2014 Order at 3:6-7 (limiting discovery on general causation issue to that of "the link between the Defendants' pharmaceuticals and pancreatic cancer") (emphasis added). Subject to and without waiving the foregoing objections, Amylin responds as follows: Amylin denies that it is in discussions with the FDA about adding a warning for pancreatic cancer to the label for Byetta®.

ELI LILLY'S RESPONSE:

Denied.

MERCK'S RESPONSE:

Merck objects to this Request for Admission because it seeks information of any event other than pancreatic cancer. Merck denies that it is in discussions with the FDA about adding a warning for pancreatic cancer to the label for JANUVIA® or JANUMET®.

NOVO'S RESPONSE:

NNI objects to this Request to the extent that it exceeds the number permitted under Southern District of California Local Rule of Civil Procedure 36.1, which limits the number of permitted Requests for Admissions to 25. NNI further objects to this Request to the extent it seeks information unrelated to pancreatic cancer. NNI denies that it is in discussions with the FDA about adding a warning for pancreatic cancer to the label for Victoza®.

REQUEST FOR ADMISSION NO. 31:
YOU are not in discussions with the FDA about adding a warning for all cancers to the label for BYETTA.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Request for Admission as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information not related to pancreatic cancer. Information regarding events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. See 8/14/2014 Order at 2:12-19 (defining discovery on preemption issue as question of "what the FDA had or did not have before it on the use of incretin-mimetic therapies and the causal association with pancreatic cancer") (emphasis added); 3/25/2014 Order at 3:6-7 (limiting discovery on general causation issue to that of "the link between the Defendants' pharmaceuticals and pancreatic cancer") (emphasis added). Subject to and without waiving the foregoing objections, Amylin responds as follows: Amylin admits that it is not in discussions with the FDA about adding a warning for pancreatic cancer to the label for Byetta®.

ELI LILLY'S RESPONSE:

Admitted.

MERCK'S RESPONSE:

Merck objects to this Request for Admission to the extent it seeks information of any event other than pancreatic cancer. Merck admits that it is not in discussion with the FDA about adding a warning for pancreatic cancer to the label for JANUVIA® or JANUMET®.

NOVO'S RESPONSE:

NNI objects to this Request to the extent that it exceeds the number permitted under Southern District of California Local Rule of Civil Procedure 36.1, which limits the number of permitted Requests for Admissions to 25. NNI further objects to this Request to the extent it seeks information unrelated to pancreatic cancer. NNI admits that it is not in discussions with the FDA about adding a warning for pancreatic cancer to the label for Victoza®.

REQUEST FOR ADMISSION NO. 32:

YOU are in discussions with the EMA about adding a warning for all cancers to the label for BYETTA.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Request for Admission as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information about communications with regulatory agencies outside the United States, as all relevant events in these cases occurred in the United States. Actions by regulatory bodies outside the United States do not override determinations or assessments made by the FDA about the label for a prescription drug marketed in the United States, and therefore have no bearing on the preemption issues in this litigation. Nor do the opinions of foreign regulatory bodies about the requirements of their respective regulations with respect to the contents of a label for a product sold in their respective country have any bearing on the general causation issues involved in this litigation.

Amylin further objects to this Request for Admission as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information not related to pancreatic cancer. Information regarding events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. See 8/14/2014 Order at 2:12-19 (defining discovery on preemption issue as question of "what the FDA had or did not have before it on the use of incretinmimetic therapies and the causal association with pancreatic cancer") (emphasis added); 3/25/2014 Order at 3:6-7 (limiting discovery on general causation issue to that of "the link between the Defendants' pharmaceuticals and pancreatic cancer") (emphasis added).

Amylin is producing its EMA regulatory files under the unique and specific facts of this case – namely, that Amylin has noted the EMA's July 2013 conclusion that Byetta® and other incretin-based therapies do not cause pancreatic cancer, as well as the February 2014 statement jointly authored by the EMA and the FDA that rejects the hypothesized associations between pancreatic cancer and Byetta® and other incretin therapies that underlie Plaintiffs' claims. Amylin continues to maintain that regulatory filings with foreign agencies are irrelevant to products liability actions in the United States and generally should not be produced in such litigation.

ELI LILLY'S RESPONSE:

Lilly objects to this request as beyond the scope of general causation or preemption as defined in the Order Following August 14, 2014 Case Management Conference (Dkt. 567). The labeling of pharmaceutical products in foreign countries is subject to differing regulatory standards than those set forth and administered by the FDA. As a result, submissions and communications with foreign regulatory agencies generally are irrelevant in U.S. product liability litigation.

MERCK'S RESPONSE:

Merck objects to this Request for Admission to the extent it seeks information concerning regulatory agencies outside of the United States and events other than pancreatic cancer. Merck's regulatory filings with foreign agencies are irrelevant to this litigation, which involves product liability lawsuits asserted under applicable U.S. law.

NOVO'S RESPONSE:

NNI objects to this Request to the extent that it exceeds the number permitted under Southern District of California Local Rule of Civil Procedure 36.1, which limits the number of permitted Requests for Admissions to 25. NNI further objects to this Request to the extent it seeks information unrelated to pancreatic cancer. NNI further objects to this Request because it seeks information regarding regulatory authorities other than the FDA. NNI maintains its position that its regulatory submissions, requirements, or activities, other than those concerning the FDA, are irrelevant to the issues of general causation and preemption. NNI further states that foreign regulatory activities are irrelevant to product liability actions pending in the United States.

REQUEST FOR ADMISSION NO. 33:

YOU are not in discussions with the EMA about adding a warning for all cancers to the label for BYETTA.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Request for Admission as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information about communications with regulatory agencies outside the United States, as all relevant events in these cases occurred in the United States. Actions by regulatory bodies outside the United States do not override determinations or assessments made by the FDA about the label for a prescription drug marketed in the United States, and therefore have no bearing on the preemption issues in this litigation. Nor do the opinions of foreign regulatory bodies about the requirements of their respective regulations with respect to the contents of a label for a product sold in their respective country have any bearing on the general causation issues involved in this litigation.

Amylin is producing its EMA regulatory files under the unique and specific facts of this case – namely, that Amylin has noted the EMA's July 2013 conclusion that Byetta® and other incretin-based therapies do not cause pancreatic cancer, as well as the February 2014 statement jointly authored by the EMA and the FDA that rejects the hypothesized associations between pancreatic cancer and Byetta® and other incretin therapies that underlie Plaintiffs' claims. Amylin continues to maintain that regulatory filings with foreign agencies are irrelevant to products liability actions in the United States and generally should not be produced in such litigation.

Amylin further objects to this Request for Admission as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information not related to pancreatic cancer. Information regarding events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. See 8/14/2014 Order at 2:12-19 (defining discovery on preemption issue as question of "what the FDA had or did not have before it on the use of incretinmimetic therapies and the causal association with pancreatic cancer") (emphasis added); 3/25/2014 Order at 3:6-7 (limiting discovery on general causation issue to that of "the link between the Defendants' pharmaceuticals and pancreatic cancer") (emphasis added).

ELI LILLY'S RESPONSE:

Lilly objects to this request as beyond the scope of general causation or preemption as defined in the Order Following August 14, 2014 Case Management Conference (Dkt. 567). The labeling of pharmaceutical products in foreign countries is subject to differing regulatory standards than those set forth and administered by the FDA. As a result, submissions and communications with foreign regulatory agencies generally are irrelevant in U.S. product liability litigation.

MERCK'S RESPONSE:

Merck objects to this Request for Admission because it seeks information concerning regulatory agencies outside of the United States and events other than pancreatic cancer. Merck's regulatory filings with foreign agencies are irrelevant to this litigation, which involves product liability lawsuits asserted under applicable U.S. law.

NOVO'S RESPONSE:

NNI objects to this Request to the extent that it exceeds the number permitted under Southern District of California Local Rule of Civil Procedure 36.1, which limits the number of permitted Requests for Admissions to 25. NNI further objects to this Request to the extent it seeks information unrelated to pancreatic cancer. NNI further objects to this Request because it seeks information regarding regulatory authorities other than the FDA. NNI maintains its position that its regulatory submissions, requirements, or activities, other than those concerning the FDA, are irrelevant to the issues of general causation and preemption. NNI further states that foreign regulatory activities are irrelevant to product liability actions pending in the United States.

REQUEST FOR ADMISSION NO. 34:

YOU are in discussions with regulatory bodies outside the United States about adding a warning for pancreatic cancer to the label for BYETTA.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Request for Admission as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information about communications with regulatory agencies outside the United States, as all relevant events in these cases occurred in the United States. Actions by regulatory bodies outside the United States do not override determinations or assessments made by the FDA about the label for a prescription drug marketed in the United States, and therefore have no bearing on the preemption issues in this litigation. Nor do the opinions of foreign regulatory bodies about the requirements of their respective regulations with respect to the contents of a label for a product sold in their respective country have any bearing on the general causation issues involved in this litigation.

ELI LILLY'S RESPONSE:

Lilly objects to this request as beyond the scope of preemption or general causation discovery defined in the Order Following August 14, 2014 Case Management Conference (Dkt. 567). The labeling of pharmaceutical products in foreign countries is subject to differing regulatory standards than those set forth and administered by the FDA. As a result, submissions and communications with foreign regulatory agencies generally are irrelevant in U.S. product liability litigation.

MERCK'S RESPONSE:

Merck objects to this Request for Admission because it seeks information concerning regulatory agencies outside of the United States. Merck's regulatory filings with foreign agencies are irrelevant to this litigation, which involves product liability lawsuits asserted under applicable U.S. law.

NOVO'S RESPONSE:

NNI objects to this Request to the extent that it exceeds the number permitted under Southern District of California Local Rule of Civil Procedure 36.1, which limits the number of permitted Requests for Admissions to 25. NNI further objects to this Request to the extent it seeks information unrelated to pancreatic cancer. NNI further objects to this Request because it seeks information regarding regulatory authorities other than the FDA. NNI maintains its position that its

regulatory submissions, requirements, or activities, other than those concerning the FDA, are irrelevant to the issues of general causation and preemption. NNI further states that foreign regulatory activities are irrelevant to product liability actions pending in the United States.

REQUEST FOR ADMISSION NO. 35:

YOU are not in discussions with regulatory bodies outside the United States about adding a warning for pancreatic cancer to the label for BYETTA.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Request for Admission as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information about communications with regulatory agencies outside the United States, as all relevant events in these cases occurred in the United States. Actions by regulatory bodies outside the United States do not override determinations or assessments made by the FDA about the label for a prescription drug marketed in the United States, and therefore have no bearing on the preemption issues in this litigation. Nor do the opinions of foreign regulatory bodies about the requirements of their respective regulations with respect to the contents of a label for a product sold in their respective country have any bearing on the general causation issues involved in this litigation.

ELI LILLY'S RESPONSE:

Lilly objects to this request as beyond the scope of preemption or general causation discovery defined in the Order Following August 14, 2014 Case Management Conference (Dkt. 567). The labeling of pharmaceutical products in foreign countries is subject to differing regulatory standards than those set forth and administered by the FDA. As a result, submissions and communications with foreign regulatory agencies generally are irrelevant in U.S. product liability litigation.

MERCK'S RESPONSE:

Merck objects to this Request for Admission because it seeks information concerning regulatory agencies outside of the United States. Merck maintains its position that regulatory filings with foreign agencies are generally irrelevant to product liability actions in the United States.

NOVO'S RESPONSE:

NNI objects to this Request to the extent that it exceeds the number permitted under Southern District of California Local Rule of Civil Procedure 36.1, which limits the number of permitted Requests for Admissions to 25. NNI further objects to this Request to the extent it seeks information unrelated to pancreatic cancer. NNI further objects to this Request because it seeks information regarding regulatory authorities other than the FDA. NNI maintains its position that its

regulatory submissions, requirements, or activities, other than those concerning the FDA, are irrelevant to the issues of general causation and preemption. NNI further states that foreign regulatory activities are irrelevant to product liability actions pending in the United States.

REQUEST FOR ADMISSION NO. 36:

YOU are in discussions with regulatory bodies outside the United States about adding a warning for all cancers to the label for BYETTA.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Request for Admission as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information about communications with regulatory agencies outside the United States, as all relevant events in these cases occurred in the United States. Actions by regulatory bodies outside the United States do not override determinations or assessments made by the FDA about the label for a prescription drug marketed in the United States, and therefore have no bearing on the preemption issues in this litigation. Nor do the opinions of foreign regulatory bodies about the requirements of their respective regulations with respect to the contents of a label for a product sold in their respective country have any bearing on the general causation issues involved in this litigation.

Amylin further objects to this Request for Admission as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information not related to pancreatic cancer. Information regarding events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. See 8/14/2014 Order at 2:12-19 (defining discovery on preemption issue as question of "what the FDA had or did not have before it on the use of incretinmimetic therapies and the causal association with pancreatic cancer") (emphasis added); 3/25/2014 Order at 3:6-7 (limiting discovery on general causation issue to that of "the link between the Defendants' pharmaceuticals and pancreatic cancer") (emphasis added).

ELI LILLY'S RESPONSE:

Lilly objects to this request as beyond the scope of preemption or general causation discovery defined in the Order Following August 14, 2014 Case Management Conference (Dkt. 567). The labeling of pharmaceutical products in foreign countries is subject to differing regulatory standards than those set forth and administered by the FDA. As a result, submissions and communications with foreign regulatory agencies generally are irrelevant in U.S. product liability litigation.

MERCK'S RESPONSE:

Merck objects to this Request for Admission because it seeks information concerning regulatory agencies outside of the United States and events other than pancreatic cancer. Merck's regulatory filings with foreign agencies are irrelevant to this litigation, which involves product liability lawsuits asserted under applicable U.S. law.

NOVO'S RESPONSE:

NNI objects to this Request to the extent that it exceeds the number permitted under Southern District of California Local Rule of Civil Procedure 36.1, which limits the number of permitted Requests for Admissions to 25. NNI further objects to this Request to the extent it seeks information unrelated to pancreatic cancer. NNI further objects to this Request because it seeks information regarding regulatory authorities other than the FDA. NNI maintains its position that its regulatory submissions, requirements, or activities, other than those concerning the FDA, are irrelevant to the issues of general causation and preemption. NNI further states that foreign regulatory activities are irrelevant to product liability actions pending in the United States.

REQUEST FOR ADMISSION NO. 37:

YOU are not in discussions with regulatory bodies outside the United States about adding a warning for all cancers to the label for BYETTA.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Request for Admission as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information about communications with regulatory agencies outside the United States, as all relevant events in these cases occurred in the United States. Actions by regulatory bodies outside the United States do not override determinations or assessments made by the FDA about the label for a prescription drug marketed in the United States, and therefore have no bearing on the preemption issues in this litigation. Nor do the opinions of foreign regulatory bodies about the requirements of their respective regulations with respect to the contents of a label for a product sold in their respective country have any bearing on the general causation issues involved in this litigation.

Amylin further objects to this Request for Admission as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information not related to pancreatic cancer. Information regarding events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. See 8/14/2014 Order at 2:12-19 (defining discovery on preemption issue as question of "what the FDA had or did not have before it on the use of incretinmimetic therapies and the causal association with pancreatic cancer") (emphasis added); 3/25/2014 Order at 3:6-7 (limiting discovery on general causation issue to that of "the link between the Defendants' pharmaceuticals and pancreatic cancer") (emphasis added).

ELI LILLY'S RESPONSE:

Lilly objects to this request as beyond the scope of preemption or general causation discovery defined in the Order Following August 14, 2014 Case Management Conference (Dkt. 567). The labeling of pharmaceutical products in foreign countries is subject to differing regulatory standards than those set forth and administered by the FDA. As a result, submissions and communications with foreign regulatory agencies generally are irrelevant in U.S. product liability litigation.

MERCK'S RESPONSE:

Merck objects to this Request for Admission because it seeks information concerning regulatory agencies outside of the United States. Merck's regulatory filings with foreign agencies are irrelevant to this litigation, which involves product liability lawsuits asserted under applicable U.S. law.

NOVO'S RESPONSE:

NNI objects to this Request to the extent that it exceeds the number permitted under Southern District of California Local Rule of Civil Procedure 36.1, which limits the number of permitted Requests for Admissions to 25. NNI further objects to this Request to the extent it seeks information unrelated to pancreatic cancer. NNI further objects to this Request because it seeks information regarding regulatory authorities other than the FDA. NNI maintains its position that its regulatory submissions, requirements, or activities, other than those concerning the FDA, are irrelevant to the issues of general causation and preemption. NNI further states that foreign regulatory activities are irrelevant to product liability actions pending in the United States.

INTERROGATORY NO. 2:

Describe the REASONABLE EVIDENCE OF A CAUSAL ASSOCIATION for each "serious side effect" identified in the Medication Guide for BYETTA.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Interrogatory as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information not related to pancreatic cancer. Description of the causal association for and FDA's actions with respect to events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. See 8/14/2014 Order at 2:12-19 (defining discovery on preemption issue as question of "what the FDA had or did not have before it on the use of incretin-mimetic therapies and the causal association with pancreatic cancer") (emphasis added); 3/25/2014 Order at 3:6-7 (limiting discovery on general causation issue to that of "the link between the Defendants' pharmaceuticals and pancreatic cancer") (emphasis added).

Subject to and without waiving the foregoing objections, Amylin responds as follows: Pancreatic cancer is not listed as a "serious side effect" in the Medication Guide for Byetta®. Further, as the FDA has recently stated, there is no reasonable evidence of a causal association between pancreatic cancer and Byetta®. See Amy G. Egan, et al., Pancreatic Safety of Incretin-Based Drugs—FDA and EMA Assessment, N. Eng. J. Med. 794 (Feb. 27, 2014)

ELI LILLY'S RESPONSE:

Lilly objects to this interrogatory to the extent it seeks information on any event other than pancreatic cancer as overbroad, irrelevant and unduly burdensome. FDA's actions with respect to events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation as defined in the Order Following August 14, 2014 Case Management Conference (Dkt. 567). As limited to information concerning pancreatic cancer, Lilly states that pancreatic cancer is not listed in the Medication Guide for Byetta. Further, there is no reasonable evidence of a causal association between pancreatic cancer and Byetta, and with respect to allegations of such a causal association, the FDA has stated that it believes "that the current knowledge is adequately reflected in the product information or labeling." Egan, et al., Pancreatic Safety of Incretin-Based Drugs – FDA and EMA Assessment, N. ENGL. J. MED. 370:9 (Feb. 27, 2014). To the extent this interrogatory seeks information about submissions to the FDA regarding Byetta, Lilly objects to this request as misdirected to it, and refers Plaintiffs to Amylin, the regulatory approval holder for Byetta in the United States, for the information sought by this interrogatory.

MERCK'S RESPONSE:

Merck objects to this Interrogatory to the extent it seeks information on any event other than pancreatic cancer as being unduly burdensome, overly broad and irrelevant. FDA's actions with respect to other Merck products or events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. As limited to information concerning JANUVIA® or JANUMET® and pancreatic cancer, Merck states pancreatic cancer is not listed as a "serious side effect" in the Medication Guide for JANUVIA® or JANUMET®. Further, there is no reasonable evidence of a causal association between pancreatic cancer and JANUVIA® or JANUMET®.

NOVO'S RESPONSE:

NNI incorporates, as if fully set forth herein, the General Objections by reference. NNI further objects to this Interrogatory as overly broad and not relevant to the issues of general causation and preemption to the extent it seeks information unrelated to pancreatic cancer. Subject to and without waiving or otherwise limiting the foregoing General and Specific Objections, NNI states that the FDA's actions with respect to events other than pancreatic cancer are not germane to the issues of general causation and preemption in this litigation. NNI further states that pancreatic cancer is not identified as a "serious side effect" in the Medication Guide for Victoza® because there is no reasonable evidence of a causal association between Victoza® and pancreatic cancer.

INTERROGATORY NO. 3:

In the past 8 years, have YOU ever submitted to the FDA a LABEL SUBMISSION that included a request for a "serious side effect" to be identified in the Medication Guide for one of YOUR branded prescription drugs, when YOU did not believe there was REASONABLE EVIDENCE OF A CAUSAL ASSOCIATION between the "serious side effect" and YOUR drug? If so, identify each such LABEL SUBMISSION, and explain why you made each such LABEL SUBMISSION.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Interrogatory as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information not related to Byetta® and pancreatic cancer. FDA's actions with respect to drugs other than Byetta® and events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. See 8/14/2014 Order at 2:12-19 (defining discovery on preemption issue as question of "what the FDA had or did not have before it on the use of incretin-mimetic therapies and the causal association with pancreatic cancer") (emphasis added); 3/25/2014 Order at 3:6-7 (limiting discovery on general causation issue to that of "the link between the Defendants' pharmaceuticals and pancreatic cancer") (emphasis added).

Subject to and without waiving the foregoing objections, Amylin responds as follows: Amylin has not proposed that a warning for pancreatic cancer be added to the Byetta® label. Further, as the FDA has recently stated, there is no reasonable evidence of a causal association between pancreatic cancer and Byetta®. See Amy G. Egan, et al., Pancreatic Safety of Incretin-Based Drugs—FDA and EMA Assessment, N. Eng. J. Med. 794 (Feb. 27, 2014).

ELI LILLY'S RESPONSE:

Lilly objects to this interrogatory as overbroad, irrelevant, and unduly burdensome to the extent it seeks information related to medications other than Byetta and any event other than pancreatic cancer. FDA's actions with respect to other medications and events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation as defined in the Order Following August 14, 2014 Case Management Conference (Dkt. 567). To the extent this interrogatory seeks information about submissions to the FDA regarding Byetta, Lilly objects to this request as misdirected to it, and refers Plaintiffs to Amylin, the regulatory approval holder for Byetta in the United States, for the information sought by this interrogatory. As limited to information

concerning Byetta and pancreatic cancer, Lilly states pancreatic cancer is not listed in the Medication Guide for Byetta. Further, there is no reasonable evidence of a causal association between pancreatic cancer and Byetta, and with respect to allegations of such a causal association, the FDA has stated that it believes "that the current knowledge is adequately reflected in the product information or labeling." Egan, et al., Pancreatic Safety of Incretin-Based Drugs – FDA and EMA Assessment, N. ENGL. J. MED. 370:9 (Feb. 27, 2014).

MERCK'S RESPONSE:

Merck objects to this Interrogatory to the extent it seeks information on drugs other than JANUVIA® or JANUMET® and on any event other than pancreatic cancer as being unduly burdensome, overly broad and irrelevant. FDA's actions with respect to other Merck products or events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. As limited to information concerning JANUVIA® or JANUMET® and pancreatic cancer, Merck states that it has not submitted to the FDA a LABEL SUBMISSION that included a request for pancreatic cancer to be listed as a "serious side effect" in the Medication Guide for JANUVIA® or JANUMET®.

NOVO'S RESPONSE:

NNI incorporates, as if fully set forth herein, the General Objections by reference. NNI further objects to this Interrogatory as overly broad and unduly burdensome. NNI further objects to this Interrogatory as not relevant to the issues of general causation and preemption to the extent it seeks information unrelated to pancreatic cancer and regarding products other than Victoza®. NNI further objects to the extent that Medication Guides do not exist as part of the required product labeling for NNI drugs other than Victoza®.

Subject to and without waiving or otherwise limiting the foregoing General and Specific Objections, NNI states that the FDA's actions with respect to NNI products other than Victoza® or events other than pancreatic cancer are not germane to the issues of general causation and preemption in this litigation. NNI will limit its response to pancreatic cancer and Victoza®. NNI further states that it has not submitted a request to the FDA to include pancreatic cancer as a serious side effect of Victoza® in the Medication Guide because there is no reasonable evidence of a causal association between Victoza® and pancreatic cancer.

By way of further answer, NNI states that the FDA, in denying the Public Citizen petition to withdraw Victoza® from the market, expressly stated that it had found "no new evidence regarding the risk of pancreatic carcinoma . . . that would support any changes to the current approved labeling" for Victoza®. See Letter from Janet Woodcock, Dir., FDA Ctr. for Drug Eval. & Res., to Elizabeth

Barbehenn & Sidney M. Wolfe, Public Citizen's Health Res. Grp. at 26 (Mar. 25, 2014) (hereinafter "FDA Response to Citizen Petition"). Further, in a statement published in February 2014 in the New England Journal of Medicine, which was based on a comprehensive review of the scientific evidence, the FDA concluded that a causal association between Victoza® and pancreatic cancer is "inconsistent with the current data" and expressly stated that the approved labeling for Victoza®—which does not include any reference to pancreatic cancer—adequately reflects current knowledge regarding the pancreatic safety of the medication. See Amy Egan, M.D., M.P.H., et al. Pancreatic Safety of Incretin-Based Drugs –FDA and EMA Assessment, 370:9 NEW. ENG. J.MED. 794, 796 (2014) (hereinafter "FDA and EMA Assessment"); see also 21 C.F.R. § 201.57(c)(6)(i) (permitting a change to the Warnings and Precautions section of a label only if there is "reasonable evidence of a causal association with a drug"). These express statements are clear evidence the FDA would not approve the addition of a pancreatic cancer warning (or other information) to the Victoza® product labeling.

NNI further refers Plaintiffs to its communications and submissions to the FDA regarding Victoza®, which are produced at Bates ranges NNI-IND-61040-00000001- 00060258 and NNI-NDA-22341-00000001-01384489 and which include communications and submissions related to the Medication Guide for Victoza®. NNI also refers Plaintiffs to NNI's Product Label and Medication Guide production, produced to Plaintiffs at NNI-Label 00000001-24 for all FDA-approved product labels and Medication Guides for Victoza®.

INTERROGATORY NO. 4:

In the past 8 years, has the FDA ever required a warning for a "serious side effect" to be identified in the Medication Guide of one of YOUR branded prescription drugs for which YOU did not believe there was REASONABLE EVIDENCE OF A CAUSAL ASSOCIATION between the "serious side effect" and YOUR drug? If so, identify each such drug and required warning, and identify all communications YOU had with the FDA regarding each such drug and required warning.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Interrogatory as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information not related to Byetta® and pancreatic cancer. FDA's actions with respect to drugs other than Byetta® and events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. See 8/14/2014 Order at 2:12-19 (defining discovery on preemption issue as question of "what the FDA had or did not have before it on the use of incretin-mimetic therapies and the causal association with pancreatic cancer") (emphasis added); 3/25/2014 Order at 3:6-7 (limiting discovery on general causation issue to that of "the link between the Defendants' pharmaceuticals and pancreatic cancer") (emphasis added).

Subject to and without waiving the foregoing objections, Amylin responds as follows: FDA has not required a warning for pancreatic cancer, nor has it required that pancreatic cancer be identified as a "serious side effect" in the Medication Guide for Byetta®. Further, as the FDA has recently stated, there is no reasonable evidence of a causal association between pancreatic cancer and Byetta®. Amy G. Egan, et al., Pancreatic Safety of Incretin-Based Drugs—FDA and EMA Assessment, N. Eng. J. Med. 794 (Feb. 27, 2014).

ELI LILLY'S RESPONSE:

Lilly objects to this interrogatory as overbroad, irrelevant, and unduly burdensome to the extent it seeks information related to medications other than Byetta and any event other than pancreatic cancer. FDA's actions with respect to other medications and events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation as defined in the Order Following August 14, 2014 Case Management Conference (Dkt. 567). To the extent this interrogatory seeks information about submissions to the FDA regarding Byetta, Lilly objects to this request as misdirected to it, and refers Plaintiffs to Amylin, the regulatory approval holder for Byetta in the United States, for the information sought by this interrogatory. As limited to information

concerning Byetta and pancreatic cancer, Lilly states pancreatic cancer is not listed in the Medication Guide for Byetta. Further, there is no reasonable evidence of a causal association between pancreatic cancer and Byetta, and with respect to allegations of such a causal association, the FDA has stated that it believes "that the current knowledge is adequately reflected in the product information or labeling." Egan, et al., Pancreatic Safety of Incretin-Based Drugs – FDA and EMA Assessment, N. ENGL. J. MED. 370:9 (Feb. 27, 2014).

MERCK'S RESPONSE:

Merck objects to this Interrogatory to the extent it seeks information on drugs other than JANUVIA® or JANUMET® and on any event other than pancreatic cancer as being unduly burdensome, overly broad and irrelevant. FDA's actions with respect to other Merck products or events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. As limited to information concerning JANUVIA® or JANUMET® and pancreatic cancer, Merck states that it has not submitted to the FDA a label submission that included a request for pancreatic cancer to be listed as a "serious side effect" in the Medication Guide for JANUVIA® or JANUMET®.

NOVO'S RESPONSE:

NNI incorporates, as if fully set forth herein, the General Objections by reference. NNI further objects to this Interrogatory as overly broad and unduly burdensome. NNI further objects to this Interrogatory as it is not relevant to the issues of general causation and preemption to the extent it seeks information unrelated to pancreatic cancer and regarding products other than Victoza®. NNI further objects to the extent that Medication Guides do not exist as part of the required product labeling for NNI drugs other than Victoza®.

Subject to and without waiving the foregoing General and Specific Objections, NNI states that the FDA's actions with respect to NNI products other than Victoza® or events other than pancreatic cancer are not germane to the issues of general causation and preemption in this litigation. NNI will limit its response to pancreatic cancer and Victoza®. NNI further states that reasonable evidence of a causal association between Victoza® and pancreatic cancer does not exist. NNI further states that the FDA has never required that NNI include a warning for pancreatic cancer as a serious side effect in the Medication Guide for Victoza®.

By way of further answer, NNI states that the FDA, in denying the Public Citizen petition to withdraw Victoza® from the market, expressly stated that it had found "no new evidence regarding the risk of pancreatic carcinoma . . . that would support any changes to the current approved labeling" for Victoza®. See FDA Response to Citizen Petition. Further, in a statement published in February 2014 in

the New England Journal of Medicine, which was based on a comprehensive review of the scientific evidence, the FDA concluded that a causal association between Victoza® and pancreatic cancer is "inconsistent with the current data" and expressly stated that the approved labeling for Victoza®—which does not include any reference to pancreatic cancer—adequately reflects current knowledge regarding the pancreatic safety of the medication. See FDA and EMA Assessment; see also 21 C.F.R. § 201.57(c)(6)(i) (permitting a change to the Warnings and Precautions section of a label only if there is "reasonable evidence of a causal association with a drug"). These express statements are clear evidence the FDA would not approve the addition of a pancreatic cancer warning (or other information) to the Victoza® product labeling.

NNI further refers Plaintiffs to its communications and submissions to the FDA regarding Victoza®, which are produced at Bates ranges NNI-IND-61040-00000001- 00060258 and NNI-NDA-22341-00000001-01384489 and which include communications and submissions related to the Medication Guide for Victoza®. NNI also refers Plaintiffs to NNI's Product Label and Medication Guide production, produced to Plaintiffs at NNI-Label 00000001-24 for all FDA-approved product labels and Medication Guides for Victoza®.

INTERROGATORY NO. 5:

In the past 8 years, has the FDA refused a warning YOU proposed be added to the label of one of YOUR branded prescription drugs to address a serious side effect" in the drug's Medication Guide because, in the FDA's view, there was no REASONABLE EVIDENCE OF A CAUSAL ASSOCIATION between the "serious side effect" and YOUR drug? If so, identify each such drug and refused warning, and identify all communications YOU had with the FDA regarding each such drug and refused warning.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Interrogatory as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information not related to Byetta® and pancreatic cancer. FDA's actions with respect to drugs other than Byetta® and events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. See 8/14/2014 Order at 2:12-19 (defining discovery on preemption issue as question of "what the FDA had or did not have before it on the use of incretin-mimetic therapies and the causal association with pancreatic cancer") (emphasis added); 3/25/2014 Order at 3:6-7 (limiting discovery on general causation issue to that of "the link between the Defendants' pharmaceuticals and pancreatic cancer") (emphasis added).

Subject to and without waiving the foregoing objections, Amylin responds as follows: Amylin has not proposed that a warning for pancreatic cancer be added to the Byetta® label. Further, as the FDA has recently stated, there is no reasonable evidence of a causal association between pancreatic cancer and Byetta®. See Amy G. Egan, et al., Pancreatic Safety of Incretin-Based Drugs—FDA and EMA Assessment, N. Eng. J. Med. 794 (Feb. 27, 2014).

ELI LILLY'S RESPONSE:

Lilly objects to this interrogatory as overbroad, irrelevant, and unduly burdensome to the extent it seeks information on medications other than Byetta and any event other than pancreatic cancer. FDA's actions with respect to other medications and events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation as defined in the Order Following August 14, 2014 Case Management Conference (Dkt. 567). To the extent this interrogatory seeks information about submissions to the FDA regarding Byetta, Lilly objects to this request as misdirected to it, and refers Plaintiffs to Amylin, the regulatory approval holder for Byetta in the United States, for the information sought by this interrogatory. As limited to information

concerning Byetta and pancreatic cancer, Lilly states pancreatic cancer is not listed in the Medication Guide for Byetta. Further, there is no reasonable evidence of a causal association between pancreatic cancer and Byetta, and with respect to allegations of such a causal association, the FDA has stated that it believes "that the current knowledge is adequately reflected in the product information or labeling." Egan, et al., Pancreatic Safety of Incretin-Based Drugs – FDA and EMA Assessment, N. ENGL. J. MED. 370:9 (Feb. 27, 2014).

MERCK'S RESPONSE:

Merck objects to this Interrogatory to the extent it seeks information on drugs other than JANUVIA® or JANUMET® and on any event other than pancreatic cancer as being unduly burdensome, overly broad and irrelevant. FDA's actions with respect to other Merck products or events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. As limited to information concerning JANUVIA® or JANUMET® and pancreatic cancer, Merck states that it has not submitted to the FDA a label submission that included a request for pancreatic cancer to be listed as a "serious side effect" in the Medication Guide for JANUVIA® or JANUMET®.

NOVO'S RESPONSE:

NNI incorporates, as if fully set forth herein, the General Objections by reference. NNI further objects to this Interrogatory as overly broad and unduly burdensome. NNI further objects to this Interrogatory as it is not relevant to the issues of general causation and preemption to the extent it seeks information unrelated to pancreatic cancer and regarding products other than Victoza®. NNI further objects to the extent this information is not within NNI's custody or control. NNI further objects to the extent that Medication Guides do not exist as part of the required product labeling for NNI drugs other than Victoza®.

Subject to and without waiving the foregoing General and Specific Objections, NNI states that the FDA's actions with respect to NNI products other than Victoza® or events other than pancreatic cancer are not germane to the issues of general causation and preemption in this litigation. NNI will limit its response to pancreatic cancer and Victoza®. NNI states that there is no reasonable evidence of a causal association between Victoza® and pancreatic cancer, and on that basis, NNI is not required to propose, nor has it proposed, to the FDA to include pancreatic cancer as a serious side effect of Victoza® in the Medication Guide. Therefore, the FDA has not refused such a proposal by NNI to include pancreatic cancer as a serious side effect of Victoza® in the Medication Guide.

By way of further answer, NNI states that the FDA, in denying the Public Citizen petition to withdraw Victoza® from the market, expressly stated that it had

found “no new evidence regarding the risk of pancreatic carcinoma . . . that would support any changes to the current approved labeling” for Victoza. See FDA Response to Citizen Petition. Further, in a statement published in February 2014 in the New England Journal of Medicine, which was based on a comprehensive review of the scientific evidence, the FDA concluded that a causal association between Victoza® and pancreatic cancer is “inconsistent with the current data” and expressly stated that the approved labeling for Victoza®—which does not include any reference to pancreatic cancer—adequately reflects current knowledge regarding the pancreatic safety of the medication. See FDA and EMA Assessment; see also 21 C.F.R. § 201.57(c)(6)(i) (permitting a change to the Warnings and Precautions section of a label only if there is “reasonable evidence of a causal association with a drug”). These express statements are clear evidence the FDA would not approve the addition of a pancreatic cancer warning (or other information) to the Victoza® product labeling.

NNI further refers Plaintiffs to its communications and submissions to the FDA regarding Victoza®, which are produced at Bates ranges NNI-IND-61040-00000001- 00060258 and NNI-NDA-22341-00000001-01384489 and which include communications and submissions related to the Medication Guide for Victoza®. NNI also refers Plaintiffs to NNI’s Product Label and Medication Guide production, produced to Plaintiffs at NNI-Label 00000001-24 for all FDA-approved product labels and Medication Guides for Victoza®.

INTERROGATORY NO. 6:

If any regulatory body has requested and/or required that YOU change the label for BYETTA to add or strengthen warnings about the risks of pancreatitis, pancreatic cancer and/or all cancers that are or may be associated with the use of BYETTA, state the date on which each such label change was requested and/or required; identify and describe all oral and/or written communications YOU have had with the regulatory body regarding each such requested and/or required label change; identify all DOCUMENTS articulating the scientific basis for each such requested and/or required label change; state the date of implementation for each such requested and/or required label change that has been implemented; and explain the current status of each such requested and/or required label change that has not been implemented (e.g., still under consideration, request or requirement withdrawn; request or requirement stayed; etc).

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Interrogatory as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information related to pancreatitis or cancers other than pancreatic cancer, as such information has no bearing on the preemption and general causation issues involved in this litigation. See 8/14/2014 Order at 2:12-19 (defining discovery on preemption issue as question of "what the FDA had or did not have before it on the use of incretinmimetic therapies and the causal association with pancreatic cancer") (emphasis added); 3/25/2014 Order at 3:6-7 (limiting discovery on general causation issue to that of "the link between the Defendants' pharmaceuticals and pancreatic cancer") (emphasis added).

Amylin further objects to the Interrogatory as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information about communications with regulatory agencies outside the United States as all relevant events in these cases occurred in the United States. Actions by regulatory bodies outside the United States do not override determinations or assessments made by the FDA about the label for a prescription drug marketed in the United States, and therefore have no bearing on the preemption issues in this litigation. Nor do the opinions of foreign regulatory bodies about the requirements of their respective regulations with respect to the contents of a label for a product sold in their respective country have any bearing on the general causation issues involved in this litigation.

Subject to and without waiving the foregoing objections, Amylin responds as follows: FDA has not requested or required a change in the label for Byetta® to add or strengthen warnings about pancreatic cancer.

ELI LILLY'S RESPONSE:

Lilly objects to this interrogatory to the extent that it seeks information related to regulatory agencies outside the United States. The labeling of pharmaceutical products in foreign countries is subject to differing regulatory standards than those set forth and administered by the FDA. As a result, submissions and communications with foreign regulatory agencies generally are irrelevant in U.S. product liability litigation. Lilly further objects to this Interrogatory as overbroad, irrelevant, and unduly burdensome to the extent it seeks information on medications other than Byetta and any event other than pancreatic cancer. FDA's actions with respect to other medications and events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation as defined in the Order Following August 14, 2014 Case Management Conference (Dkt. 567). To the extent this interrogatory seeks information about submissions to the FDA regarding Byetta, Lilly objects to this request as misdirected to it, and refers Plaintiffs to Amylin, the regulatory approval holder for Byetta in the United States, for the information sought by this interrogatory. As limited to information concerning Byetta and pancreatic cancer in the United States, Lilly states pancreatic cancer is not listed in the Medication Guide for Byetta. Further, there is no reasonable evidence of a causal association between pancreatic cancer and Byetta, and with respect to allegations of such a causal association, the FDA has stated that it believes "that the current knowledge is adequately reflected in the product information or labeling." Egan, et al., Pancreatic Safety of Incretin-Based Drugs – FDA and EMA Assessment, N. ENGL. J. MED. 370:9 (Feb. 27, 2014).

MERCK'S RESPONSE:

Merck objects to this Interrogatory to the extent it seeks information about (a) requests or requirements of regulatory bodies other than FDA and (b) on any event other than pancreatic cancer as being unduly burdensome, overly broad and irrelevant. Actions by regulatory bodies outside the United States do not override determinations or assessments made by the FDA about the label for a prescription medicine marketed in the United States and, therefore, have no bearing on the preemption issues in this litigation. Nor do the opinions of foreign regulatory bodies about the requirements of their respective regulations with respect to the contents of a label for a product sold in their respective country have any bearing on the general causation issues involved in this litigation. As for events other than pancreatic cancer, FDA's actions with respect to such other events have no bearing on the preemption and general causation issues involved in this litigation. Merck further objects to this Interrogatory's request that Merck identify all documents articulating the scientific basis for each such request as being unduly burdensome,

overly broad and irrelevant. As limited to information concerning JANUVIA® or JANUMET® and pancreatic cancer, Merck states that the FDA has not requested or required a change in the label for JANUVIA or JANUMET to add or strengthen warnings about pancreatic cancer.

NOVO'S RESPONSE:

NNI incorporates, as if fully set forth herein, the General Objections by reference. NNI further objects to this Interrogatory as overly broad and unduly burdensome. NNI further objects to this Interrogatory as not relevant to the issues of general causation and preemption to the extent it seeks information unrelated to pancreatic cancer. NNI further objects to this Interrogatory as overly broad and not relevant to the extent it seeks information related to foreign regulatory submissions, requirements, activities, or the direction of foreign regulatory bodies. The actions of foreign regulatory authorities have no impact on the determinations made by the FDA about prescription drug labeling for products marketed in the United States, and thus, are not relevant to the issue of Federal preemption in the United States or the general causation issues involved in this Litigation. NNI further objects to this Interrogatory to the extent it requests NNI to identify all documents articulating the scientific basis for each request as unduly burdensome, overly broad and not relevant.

Subject to and without waiving the foregoing General and Specific Objections, with respect to FDA actions, NNI states that the FDA has not requested or required a change in the label for Victoza® to add a warning for pancreatic cancer. NNI further states that at no times has the label for Victoza® contained a warning for pancreatic cancer, and therefore, the FDA has not requested or required NNI to strengthen such a warning for pancreatic cancer in the label for Victoza®.

By way of further answer, NNI states that the FDA, in denying the Public Citizen petition to withdraw Victoza® from the market, expressly stated that it had found "no new evidence regarding the risk of pancreatic carcinoma . . . that would support any changes to the current approved labeling" for Victoza®. See FDA Response to Citizen Petition. Further, in a statement published in February 2014 in the New England Journal of Medicine, which was based on a comprehensive review of the scientific evidence, the FDA concluded that a causal association between Victoza® and pancreatic cancer is "inconsistent with the current data" and expressly stated that the approved labeling for Victoza®—which does not include any reference to pancreatic cancer—adequately reflects current knowledge regarding the pancreatic safety of the medication. See FDA and EMA Assessment; see also 21 C.F.R. § 201.57(c)(6)(i) (permitting a change to the Warnings and Precautions section of a label only if there is "reasonable evidence of a causal

association with a drug"). These express statements are clear evidence the FDA would not approve the addition of a pancreatic cancer warning (or other information) to the Victoza® product labeling.

NNI further refers Plaintiffs to NNI's responses to Interrogatories Nos. 3-6.

INTERROGATORY NO. 7:

If YOU and/or any of YOUR employees have been or are under investigation by any governmental entity or entities for any allegedly criminal and/or civil activity or other allegedly wrongful conduct with respect to BYETTA, including without limitation fraud, misrepresentation (including but without limitation, manipulation of any preclinical, nonclinical, animal, clinical, and/or post-clinical study participant selection criteria, protocols, processes, data, and/or results) and/or bribery, identify the governmental entity or entities involved; identify the person(s) you understand to be in charge of each investigation; state the reason(s) for each such investigation as you understand them; state the date on which each such investigation started; describe the current status of each such investigation; and for each such investigation that has been concluded, state how it was resolved.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Interrogatory as irrelevant to the issues of general causation or preemption that are currently the subjects of discovery in this litigation. See 8/14/2014 Order at 2:12-19 (defining discovery on preemption issue as question of "what the FDA had or did not have before it on the use of incretin-mimetic therapies and the causal association with pancreatic cancer") (emphasis added); 3/25/2014 Order at 3:6-7 (limiting discovery on general causation issue to that of "the link between the Defendants' pharmaceuticals and pancreatic cancer") (emphasis added).

ELI LILLY'S RESPONSE:

Lilly objects to this interrogatory as not reasonably calculated to lead to discovery of admissible evidence, harassing, and irrelevant to general causation or preemption as defined in the Order Following August 14, 2014 Case Management Conference (Dkt. 567). Lilly further objects to this interrogatory to the extent it seeks information protected by the attorney-client privilege and/or work product doctrine.

MERCK'S RESPONSE:

Merck objects to this Interrogatory as unrelated to the issues of general causation or preemption that are currently the subject of discovery in this MDL. Merck further objects to this Interrogatory on the basis that it is harassing.

NOVO'S RESPONSE:

NNI incorporates, as if fully set forth herein, the General Objections by reference. NNI further objects to this Interrogatory as overly broad and not reasonably calculated to lead to discoverable information. NNI further objects to

this Interrogatory as not relevant to issues in this Litigation, including issues relating to general causation and preemption. NNI further objects to this Interrogatory as harassing.

INTERROGATORY NO. 8:

If YOU and/or any of YOUR employees have been or are the subject of any Qui Tarn and/or Whistleblower actions with respect to BYETTA including without limitation fraud, misrepresentation (including but without limitation manipulation of any preclinical, nonclinical, animal, clinical, and/or post-clinical stud participant selection criteria, protocols, processes, data, and/or results) and/or bribery identify the Court(s) involved; identify the Docket Number of any such action(s); state the claims(s) and allegations) for each such action as you understand them; state the date on which each such action(s) were filed; describe the current status of each such action and for each such action that has been concluded, state how it was resolved.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Interrogatory as irrelevant to the issues of general causation or preemption that are currently the subjects of discovery in this litigation. See 8/14/2014 Order at 2:12-19 (defining discovery on preemption issue as question of "what the FDA had or did not have before it on the use of incretin-mimetic therapies and the causal association with pancreatic cancer") (emphasis added); 3/25/2014 Order at 3:6-7 (limiting discovery on general causation issue to that of "the link between the Defendants' pharmaceuticals and pancreatic cancer") (emphasis added).

ELI LILLY'S RESPONSE:

Lilly objects to this interrogatory as not reasonably calculated to lead to discovery of admissible evidence, harassing, and irrelevant to general causation or preemption as defined in the Order Following August 14, 2014 Case Management Conference (Dkt. 567). Lilly further objects to this interrogatory to the extent it seeks information protected by the attorney-client privilege and/or work product doctrine.

MERCK'S RESPONSE:

Merck objects to this Interrogatory as unrelated to the issues of general causation or preemption that are currently the subject of discovery in this MDL. Merck further objects to this Interrogatory on the basis that it is harassing.

NOVO'S RESPONSE:

NNI incorporates, as if fully set forth herein, the General Objections by reference. NNI further objects to this Interrogatory as overly broad and not reasonably calculated to lead to discoverable information. NNI further objects to this Interrogatory as not relevant to issues in this Litigation, including issues

relating to general causation and preemption. NNI further objects to this Interrogatory as harassing.

INTERROGATORY NO. 9:

If YOUR company has been the subject of a Corporate Integrity Agreement or is in the process of negotiating a Corporate Integrity Agreement which involves without limitation fraud, misrepresentation (including but without limitation, manipulation of any preclinical, nonclinical, animal, clinical, and/or post-clinical study participant selection criteria, protocols, processes, data, and/or results) and/or bribery, identify each Corporate Integrity Agreement; state the subject of each such Agreement; state each such Agreement's effective dates; and state the current status of each such Agreement.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Interrogatory as irrelevant to the issues of general causation or preemption that are currently the subjects of discovery in this litigation. See 8/14/2014 Order at 2:12-19 (defining discovery on preemption issue as question of "what the FDA had or did not have before it on the use of incretin-mimetic therapies and the causal association with pancreatic cancer") (emphasis added); 3/25/2014 Order at 3:6-7 (limiting discovery on general causation issue to that of "the link between the Defendants' pharmaceuticals and pancreatic cancer") (emphasis added).

ELI LILLY'S RESPONSE:

Lilly objects to this interrogatory as not reasonably calculated to lead to discovery of admissible evidence, harassing, and irrelevant to general causation or preemption as defined in the Order Following August 14, 2014 Case Management Conference (Dkt. 567). Lilly further objects to this interrogatory to the extent it seeks information protected by the attorney-client privilege and/or work product doctrine.

MERCK'S RESPONSE:

Merck objects to this Interrogatory as unrelated to the issues of general causation or preemption that are currently the subject of discovery in this MDL. Merck further objects to this Interrogatory on the basis that it is harassing.

NOVO'S RESPONSE:

NNI incorporates, as if fully set forth herein, the General Objections by reference. NNI further objects to this Interrogatory as overly broad and not reasonably calculated to lead to discoverable information. NNI further objects to this Interrogatory as not relevant to issues in this Litigation, including issues relating to general causation and preemption. NNI further objects to this Interrogatory as harassing. NNI further objects to the extent this Interrogatory calls

for information that is a matter of public record and is as accessible to Plaintiffs as to NNI.

REQUEST FOR PRODUCTION NO. 4:

The communications YOU have received from the FDA in the last 8 years in which the FDA refused a warning YOU proposed be added to the label of any of YOUR branded prescription drugs to address a "serious side effect" in the drug's Medication Guide because, in the FDA's view, there was no REASONABLE EVIDENCE OF A CAUSAL ASSOCIATION between the "serious adverse event" and YOUR drug.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Request as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information not related to Byetta® and pancreatic cancer. FDA's actions with respect to drugs other than Byetta® and events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. See 8/14/2014 Order at 2:12-19 (defining discovery on preemption issue as question of "what the FDA had or did not have before it on the use of incretin-mimetic therapies and the causal association with pancreatic cancer") (emphasis added); 3/25/2014 Order at 3:6-7 (limiting discovery on general causation issue to that of "the link between the Defendants' pharmaceuticals and pancreatic cancer") (emphasis added).

Subject to and without waiving the foregoing objections, Amylin responds as follows: Amylin has not proposed that a warning for pancreatic cancer be added to the Byetta® label. Further, as the FDA has recently stated, there is no reasonable evidence of a causal association between pancreatic cancer and Byetta®. See Amy G. Egan, et al., Pancreatic Safety of Incretin-Based Drugs—FDA and EMA Assessment, N. Eng. J. Med. 794 (Feb. 27, 2014); Letter from Janet Woodcock, Dir., FDA Ctr. for Drug Eval. & Res., to Elizabeth Barbehenn & Sidney M. Wolfe, Public Citizen's Health Res. Grp. (Mar. 25, 2014). To the extent that this Request seeks evidence regarding Amylin's additional communications with the FDA regarding Byetta®, Amylin refers Plaintiffs to the Byetta® and Byetta® monotherapy IND/NDA files that include correspondence at Bates numbers BY00390802-BY00403814, BY00416353-BY00426172, BY01176627-BY01178400, BY01201169-BY01216521, BY01343845-BY01343957, and BY01349025-BY01353202.

ELI LILLY'S RESPONSE:

Lilly objects to this request as overbroad, irrelevant, and unduly burdensome to the extent it seeks information related to medications other than Byetta and any event other than pancreatic cancer. FDA's actions with respect to other medications and events other than pancreatic cancer have no bearing on the

preemption and general causation issues involved in this litigation as defined in the Order Following August 14, 2014 Case Management Conference (Dkt. 567). To the extent this request seeks information about communications from the FDA regarding Byetta, Lilly objects to this request as misdirected to it, and refers Plaintiffs to Amylin, the regulatory approval holder for Byetta in the United States.

MERCK'S RESPONSE:

Merck objects to this Request to Produce to the extent it seeks information on drugs other than JANUVIA® or JANUMET® and of any event other than pancreatic cancer as being unduly burdensome, overly broad and irrelevant. FDA's actions with respect to other Merck products or events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. As limited to documents concerning JANUVIA® or JANUMET® and pancreatic cancer, Merck states that it does not have any responsive documents.

NOVO'S RESPONSE:

NNI incorporates, as if fully set forth herein, the General Objections by reference. NNI further objects to this Request as overly broad and unduly burdensome. NNI further objects to this Request as not relevant to the issues of general causation or preemption to the extent it seeks information unrelated to pancreatic cancer and regarding products other than Victoza®. NNI further objects to the extent that Medication Guides do not exist as part of the required product labeling for NNI drugs other than Victoza®.

Without waiving or otherwise limiting the foregoing General and Specific Objections, NNI states that the FDA's actions with respect to events other than pancreatic cancer or products other than Victoza® are not germane to the issues of general causation and preemption in this litigation. NNI limits it response to information regarding Victoza® and pancreatic cancer only. NNI states that there is no reasonable evidence of a causal association between Victoza® and pancreatic cancer, and on that basis, NNI is not required to propose, nor has it proposed, to include pancreatic cancer as a serious side effect of Victoza® in the Medication Guide to the FDA. Therefore, the FDA has not refused a proposal from NNI to include pancreatic cancer as a serious side effect of Victoza® in the Medication Guide. No responsive documents exist.

By way of further answer, NNI states that the FDA, in denying the Public Citizen petition to withdraw Victoza® from the market, expressly stated that it had found "no new evidence regarding the risk of pancreatic carcinoma . . . that would support any changes to the current approved labeling" for Victoza®. See Letter from Janet Woodcock, Dir., FDA Ctr. for Drug Eval. & Res., to Elizabeth Barbehenn & Sidney M. Wolfe, Public Citizen's Health Res. Grp. at 26 (Mar. 25,

2014) (hereinafter "FDA Response to Citizen Petition"). Further, in a statement published in February 2014 in the New England Journal of Medicine, which was based on a comprehensive review of the scientific evidence, the FDA concluded that a causal association between Victoza® and pancreatic cancer is "inconsistent with the current data" and expressly stated that the approved labeling for Victoza®—which does not include any reference to pancreatic cancer—adequately reflects current knowledge regarding the pancreatic safety of the medication. See Amy Egan, M.D., M.P.H., et al. Pancreatic Safety of Incretin-Based Drugs –FDA and EMA Assessment, 370:9 NEW. ENG. J.MED. 794, 796 (2014) (hereinafter "FDA and EMA Assessment"); see also 21 C.F.R. § 201.57(c)(6)(i) (permitting a change to the Warnings and Precautions section of a label only if there is "reasonable evidence of a causal association with a drug"). These express statements are clear evidence the FDA would not approve the addition of a pancreatic cancer warning (or other information) to the Victoza® product labeling.

For all of NNI's communications and submissions to the FDA regarding Victoza®, NNI refers Plaintiffs to Bates ranges NNI-IND-61040-00000001-00060258 and NNI-NDA-22341-00000001-01384489. NNI also refers Plaintiffs to NNI's Product Label and Medication Guide production, produced to Plaintiffs at NNI-Label 00000001-24 for all FDA-approved product labels and Medication Guides for Victoza®.

REQUEST FOR PRODUCTION NO. 5:

The communications YOU have received from the FDA in the last 8 years in which the FDA refused any warning YOU proposed be added to the label of any of YOUR branded prescription drugs because, in the FDA's view, there was no REASONABLE EVIDENCE OF A CAUSAL ASSOCIATION between the medical condition at issue and YOUR drug.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Request as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information not related to Byetta® and pancreatic cancer. FDA's actions with respect to drugs other than Byetta® and events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. See 8/14/2014 Order at 2:12-19 (defining discovery on preemption issue as question of "what the FDA had or did not have before it on the use of incretin-mimetic therapies and the causal association with pancreatic cancer") (emphasis added); 3/25/2014 Order at 3:6-7 (limiting discovery on general causation issue to that of "the link between the Defendants' pharmaceuticals and pancreatic cancer") (emphasis added).

Subject to and without waiving the foregoing objections, Amylin responds as follows: Amylin has not proposed that a warning for pancreatic cancer be added to the Byetta® label. Further, as the FDA has recently stated, there is no reasonable evidence of a causal association between pancreatic cancer and Byetta®. See Amy G. Egan, et al., Pancreatic Safety of Incretin-Based Drugs—FDA and EMA Assessment, N. Eng. J. Med. 794 (Feb. 27, 2014); Letter from Janet Woodcock, Dir., FDA Ctr. for Drug Eval. & Res., to Elizabeth Barbehenn & Sidney M. Wolfe, Public Citizen's Health Res. Grp. (Mar. 25, 2014). To the extent that this Request seeks evidence regarding Amylin's additional communications with the FDA regarding Byetta®, Amylin refers Plaintiffs to the Byetta® and Byetta® monotherapy IND/NDA files that include correspondence at Bates numbers BY00390802-BY00403814, BY00416353-BY00426172, BY01176627-BY01178400, BY01201169-BY01216521, BY01343845-BY01343957, and BY01349025-BY01353202.

ELI LILLY'S RESPONSE:

Lilly objects to this request as overbroad, irrelevant, and unduly burdensome to the extent it seeks information related to medications other than Byetta and any event other than pancreatic cancer. FDA's actions with respect to other medications and events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation as defined in the

Order Following August 14, 2014 Case Management Conference (Dkt. 567). To the extent this request seeks information about communications from the FDA regarding Byetta, Lilly objects to this request as misdirected to it, and refers Plaintiffs to Amylin, the regulatory approval holder for Byetta in the United States.

MERCK'S RESPONSE:

Merck objects to this Request to Produce to the extent it seeks information on drugs other than JANUVIA® or JANUMET® and of any event other than pancreatic cancer as being unduly burdensome, overly broad and irrelevant. FDA's actions with respect to other Merck products or events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. As limited to documents concerning JANUVIA® or JANUMET® and pancreatic cancer, Merck states that it does not have any responsive documents.

NOVO'S RESPONSE:

NNI incorporates, as if fully set forth herein, the General Objections by reference. NNI further objects to this Request as overly broad and unduly burdensome. NNI further objects to this Request as it is not relevant to the issues of general causation and preemption to the extent it seeks information unrelated to pancreatic cancer and regarding products other than Victoza®.

Without waiving or otherwise limiting the foregoing General and Specific Objections, NNI states that the FDA's actions with respect to events other than pancreatic cancer or products other than Victoza® are not germane to the issues of general causation and preemption in this litigation. NNI limits it response to information regarding Victoza® and pancreatic cancer only. NNI states that there is no reasonable evidence of a causal association between Victoza® and pancreatic cancer, and on that basis, NNI is not required to propose, nor has it proposed, to add a warning related to pancreatic cancer to the Victoza® label to the FDA. Therefore, the FDA has not refused a proposal from NNI to include pancreatic cancer as a warning in the Victoza® label. No responsive documents exist.

By way of further answer, NNI states that the FDA, in denying the Public Citizen petition to withdraw Victoza® from the market, expressly stated that it had found "no new evidence regarding the risk of pancreatic carcinoma . . . that would support any changes to the current approved labeling" for Victoza®. See FDA Response to Citizen Petition. Further, in a statement published in February 2014 in the New England Journal of Medicine, which was based on a comprehensive review of the scientific evidence, the FDA concluded that a causal association between Victoza® and pancreatic cancer is "inconsistent with the current data" and expressly stated that the approved labeling for Victoza®—which does not include any reference to pancreatic cancer—adequately reflects current knowledge

regarding the pancreatic safety of the medication. See FDA and EMA Assessment; see also 21 C.F.R. § 201.57(c)(6)(i) (permitting a change to the Warnings and Precautions section of a label only if there is "reasonable evidence of a causal association with a drug"). These express statements are clear evidence the FDA would not approve the addition of a pancreatic cancer warning (or other information) to the Victoza® product labeling.

For all of NNI's communications and submissions to the FDA regarding Victoza®, NNI refers Plaintiffs to Bates ranges NNI-IND-61040-00000001-00060258 and NNI-NDA-22341-00000001-01384489. NNI also refers Plaintiffs to NNI's Product Label and Medication Guide production, produced to Plaintiffs at NNI-Label 00000001-24 for all FDA-approved product labels and Medication Guides for Victoza®.

REQUEST FOR PRODUCTION NO. 6:

The communications YOU have received from the FDA that YOU contend demonstrate that the FDA believes there is no REASONABLE EVIDENCE OF ACAUSAL ASSOCIATION between pancreatic cancer and VICTOZA.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Request as vague and ambiguous, including but not limited to its use of the term "communications." Amylin further objects to the Request to the extent it seeks documents that are publicly and equally available to Plaintiffs.

Subject to and without waiving the foregoing objections, Amylin responds as follows: Amylin refers Plaintiffs to the official FDA statement published in the February 2014 issue of the New England Journal of Medicine, which provides clear evidence that the FDA does not believe there is reasonable evidence of a causal association between pancreatic cancer and Byetta®. Amy G. Egan, et al., Pancreatic Safety of Incretin-Based Drugs—FDA and EMA Assessment, N. Eng. J. Med. 794 (Feb. 27, 2014). Further, Amylin refers Plaintiffs to FDA's rejection of a Public Citizen Petition focusing on Victoza, in which FDA reaffirmed the adequacy of the current labeling for incretin-based therapies. Letter from Janet Woodcock, Dir., FDA Ctr. for Drug Eval. & Research, to Elizabeth Barbehenn & Sidney M. Wolfe, Public Citizen's Health Research Grp. (Mar. 25, 2014).

ELI LILLY'S RESPONSE:

Lilly objects to this request as misdirected to it, and refers Plaintiffs to Amylin, the regulatory approval holder for Byetta in the United States for the information sought by this request. By way of further response, Lilly refers Plaintiffs to Egan, et al., Pancreatic Safety of Incretin-Based Drugs – FDA and EMA Assessment, N. ENGL. J. MED. 370:9 (Feb. 27, 2014); and Letter from Janet Woodcock, Dir., FDA Ctr. for Drug Eval. & Res., to Elizabeth Barbehenn & Sidney M. Wolfe, Public Citizen's Health Res. Grp. (Mar. 25, 2014), both of which are publicly available.

MERCK'S RESPONSE:

To the extent not already produced as part of its NDA and IND production, Merck will produce documents responsive to this Request. That production will include statements FDA has made publicly and documents Merck has obtained from FDA in connection with a Freedom of Information Act request.

NOVO'S RESPONSE:

NNI incorporates, as if fully set forth herein, the General Objections by reference. NNI further objects to producing any documents equally available to Plaintiffs in the public domain.

NNI incorporates, as if fully set forth herein, the General Objections by reference. Without waiving or otherwise limiting the foregoing General Objections, NNI states that on February 27, 2014, NNI received a joint statement by the FDA and EMA published in the New England Journal of Medicine, which was based on a comprehensive review of available scientific evidence, in which the FDA concluded that a causal association between Victoza® and pancreatic cancer is "inconsistent with the current data" and expressly stated that the approved labeling for Victoza®—which does not include any reference to pancreatic cancer—adequately reflects current knowledge regarding the pancreatic safety of the medication. See FDA and EMA Assessment.

NNI further states that on March 25, 2014, NNI received a letter from the Director of the FDA's Center for Drug Evaluation and Research, Janet Woodcock, M.D., denying the Public Citizen petition to withdraw Victoza® from the market. This letter expressly stated that the FDA had found "no new evidence regarding the risk of pancreatic carcinoma . . . that would support any changes to the current approved labeling" for Victoza®. See FDA Response to Citizen Petition. These express statements are clear evidence the FDA would not approve the addition of a pancreatic cancer warning (or other information) to the Victoza® product labeling.

NNI further refers Plaintiffs to its communications and submissions to the FDA regarding Victoza®, which are produced at Bates ranges NNI-IND-61040-00000001- 00060258 and NNI-NDA-22341-00000001-01384489. NNI also refers Plaintiffs to NNI's Product Label and Medication Guide production, produced to Plaintiffs at NNILabel 00000001-24 for all approved product labels for Victoza®.

REQUEST FOR PRODUCTION NO. 7:

All DOCUMENTS in which the FDA instructed YOU to remove a medical condition from the Highlights, Warnings and Precautions, Adverse Reactions, Nonclinical Toxicology, Clinical Studies, Patient Counseling Information, or Medication Guide for VICTOZA.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Request as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information not related to pancreatic cancer. FDA's actions with respect to events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. See 8/14/2014 Order at 2:12-19 (defining discovery on preemption issue as question of "what the FDA had or did not have before it on the use of incretin-mimetic therapies and the causal association with pancreatic cancer") (emphasis added); 3/25/2014 Order at 3:6-7 (limiting discovery on general causation issue to that of "the link between the Defendants' pharmaceuticals and pancreatic cancer") (emphasis added).

Subject to and without waiving the foregoing objections, Amylin responds as follows: To the extent this Request seeks information on pancreatic cancer, Amylin responds that pancreatic cancer has never been included in the Highlights, Warnings and Precautions, Adverse Reactions, Nonclinical Toxicology, Clinical Studies, or Patient Counseling Information sections, or in the Medication Guide for Byetta®. Further, as the FDA has recently stated, there is no reasonable evidence of a causal association between pancreatic cancer and Byetta®. See Amy G. Egan, et al., Pancreatic Safety of Incretin-Based Drugs—FDA and EMA Assessment, N. Eng. J. Med. 794 (Feb. 27, 2014); Letter from Janet Woodcock, Dir., FDA Ctr. for Drug Eval. & Res., to Elizabeth Barbehenn & Sidney M. Wolfe, Public Citizen's Health Res. Grp. (Mar. 25, 2014).

ELI LILLY'S RESPONSE:

Lilly objects to this request as misdirected to it, and refers Plaintiffs to Amylin, the regulatory approval holder for Byetta in the United States, for the information sought by this request. Lilly further objects to this request as overbroad, irrelevant and unduly burdensome to the extent it seeks information related to any event other than pancreatic cancer. FDA's actions with respect to events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation as defined in the Order Following August 14, 2014 Case Management Conference (Dkt. 567).

MERCK'S RESPONSE:

Merck objects to this Request to Produce to the extent it seeks information of any event other than pancreatic cancer as being unduly burdensome, overly broad and irrelevant. FDA's actions with respect to events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. As limited to documents concerning pancreatic cancer, Merck states that it does not have any responsive documents.

NOVO'S RESPONSE:

NNI incorporates, as if fully set forth herein, the General Objections by reference. NNI further objects to this Request as it is not relevant to the issues of general causation and preemption to the extent it seeks information unrelated to pancreatic cancer.

Without waiving or otherwise limiting the foregoing General and Specific Objections, NNI states that the FDA's actions with respect to events other than pancreatic cancer are not germane to the issues of general causation and preemption in this litigation. NNI limits it response to information regarding Victoza® and pancreatic cancer only. NNI states that there is no reasonable evidence of a causal association between Victoza® and pancreatic cancer, and on that basis, the Highlights, Warning and Precautions, Adverse Reactions, Nonclinical Toxicology, Clinical Studies, Patient Counseling Information, and/or Medication Guide for Victoza® have never included a reference to pancreatic cancer. Therefore, the FDA has not instructed NNI to remove a reference to pancreatic cancer in the Highlights, Warnings and Precautions, Adverse Reactions, Nonclinical Toxicology, Clinical Studies, Patient Counseling Information, or Medication Guide for Victoza®. No responsive documents exist.

By way of further answer, NNI states that the FDA, in denying the Public Citizen petition to withdraw Victoza® from the market, expressly stated that it had found "no new evidence regarding the risk of pancreatic carcinoma . . . that would support any changes to the current approved labeling" for Victoza®. See FDA Response to Citizen Petition. Further, in a statement published in February 2014 in the New England Journal of Medicine, which was based on a comprehensive review of the scientific evidence, the FDA concluded that a causal association between Victoza® and pancreatic cancer is "inconsistent with the current data" and expressly stated that the approved labeling for Victoza®—which does not include any reference to pancreatic cancer—adequately reflects current knowledge regarding the pancreatic safety of the medication. See FDA and EMA Assessment; see also 21 C.F.R. § 201.57(c)(6)(i) (permitting a change to the Warnings and Precautions section of a label only if there is "reasonable evidence of a causal association with a drug"). These express statements are clear evidence the FDA

would not approve the addition of a pancreatic cancer warning (or other information) to the Victoza® product labeling.

For all of NNI's communications and submissions to the FDA regarding Victoza®, NNI refers Plaintiffs to Bates ranges NNI-IND-61040-00000001-00060258 and NNI-NDA-22341-00000001-01384489. NNI also refers Plaintiffs to NNI's Product Label and Medication Guide production, produced to Plaintiffs at NNI-Label 00000001-24 for all FDA-approved product labels and Medication Guides for Victoza®.

REQUEST FOR PRODUCTION NO. 8:

The DOCUMENTS in which the FDA rejected or discussed the rejection of any warning YOU proposed be added for VICTOZA.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Request as irrelevant, overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information not related to pancreatic cancer. FDA's actions with respect to events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. See 8/14/2014 Order at 2:12-19 (defining discovery on preemption issue as question of "what the FDA had or did not have before it on the use of incretin-mimetic therapies and the causal association with pancreatic cancer") (emphasis added); 3/25/2014 Order at 3:6-7 (limiting discovery on general causation issue to that of "the link between the Defendants' pharmaceuticals and pancreatic cancer") (emphasis added).

Subject to and without waiving the foregoing objections, Amylin responds as follows: To the extent this Request seeks information on pancreatic cancer, Amylin responds that it has not proposed that a warning for pancreatic cancer be added to the Byetta® label. Further, as the FDA has recently stated, there is no reasonable evidence of a causal association between pancreatic cancer and Byetta®. See Amy G. Egan, et al., Pancreatic Safety of Incretin-Based Drugs—FDA and EMA Assessment, N. Eng. J. Med. 794 (Feb. 27, 2014); Letter from Janet Woodcock, Dir., FDA Ctr. for Drug Eval. & Res., to Elizabeth Barbehenn & Sidney M. Wolfe, Public Citizen's Health Res. Grp. (Mar. 25, 2014).

ELI LILLY'S RESPONSE:

Lilly objects to this request as misdirected to it, and refers Plaintiffs to Amylin, the regulatory approval holder for Byetta in the United States. Lilly objects to this request as overbroad, irrelevant, and unduly burdensome to the extent it seeks information related to any event other than pancreatic cancer. FDA's actions with respect to events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation as defined in the Order Following August 14, 2014 Case Management Conference (Dkt. 567). By way of further response, Lilly refers Plaintiffs to the FDA's statement "that the current knowledge is adequately reflected in the product information or labeling." Egan, et al., Pancreatic Safety of Incretin-Based Drugs – FDA and EMA Assessment, N. ENGL. J. MED. 370:9 (Feb. 27, 2014).

MERCK'S RESPONSE:

Merck objects to this Request to Produce to the extent it seeks information of any event other than pancreatic cancer as being unduly burdensome, overly broad and irrelevant. FDA's actions with respect to events other than pancreatic cancer have no bearing on the preemption and general causation issues involved in this litigation. As limited to documents concerning pancreatic cancer, Merck states that it does not have any responsive documents.

NOVO'S RESPONSE:

NNI incorporates, as if fully set forth herein, the General Objections by reference. NNI further objects to this Request as it is not relevant to the issues of general causation and preemption to the extent it seeks information unrelated to pancreatic cancer. NNI further objects to this request to the extent it seeks information not within NNI's possession, custody, or control.

Without waiving or otherwise limiting the foregoing General and Specific Objections, NNI states that the FDA's actions with respect to events other than pancreatic cancer are not germane to the issues of general causation and preemption in this litigation. NNI limits its response to information regarding pancreatic cancer only. NNI states that there is no reasonable evidence of a causal association between Victoza® and pancreatic cancer, and on that basis, NNI is not required to propose, nor has it proposed, that a pancreatic cancer warning be included in the Victoza® labeling information to the FDA. Therefore, the FDA has not rejected a proposal from NNI to include a warning for pancreatic cancer in the Victoza® labeling information. No responsive documents exist.

By way of further answer, NNI states that the FDA, in denying the Public Citizen petition to withdraw Victoza® from the market, expressly stated that it had found "no new evidence regarding the risk of pancreatic carcinoma . . . that would support any changes to the current approved labeling" for Victoza®. See FDA Response to Citizen Petition. Further, in a statement published in February 2014 in the New England Journal of Medicine, which was based on a comprehensive review of the scientific evidence, the FDA concluded that a causal association between Victoza® and pancreatic cancer is "inconsistent with the current data" and expressly stated that the approved labeling for Victoza®—which does not include any reference to pancreatic cancer—adequately reflects current knowledge regarding the pancreatic safety of the medication. See FDA and EMA Assessment; see also 21 C.F.R. § 201.57(c)(6)(i) (permitting a change to the Warnings and Precautions section of a label only if there is "reasonable evidence of a causal association with a drug"). These express statements are clear evidence the FDA would not approve the addition of a pancreatic cancer warning (or other information) to the Victoza® product labeling.

For all of NNI's communications and submissions to the FDA regarding Victoza®, NNI refers Plaintiffs to Bates ranges NNI-IND-61040-00000001-00060258 and NNI-NDA-22341-00000001-01384489. NNI also refers Plaintiffs to NNI's Product Label and Medication Guide production, produced to Plaintiffs at NNI-Label 00000001-24 for all FDA-approved product labels and Medication Guides for Victoza®.

REQUEST FOR PRODUCTION NO. 10:

Every DOCUMENT in which an employee of, or consultant to, YOUR company recommends including a reference to pancreatic cancer in the VICTOZA Prescribing Information or Medication Guide.

AMYLIN'S RESPONSE:

Subject to the Preliminary Statement, Amylin objects to this Request as irrelevant, overbroad, unduly burdensome, and as contrary to the limited custodial approach to discovery agreed to by the parties and ordered by the Court in its 4/21/2014 Order Governing Procedures for Production of Electronically Stored Information (Doc. No. 415). Amylin further objects to the Request to the extent it seek documents outside Amylin's custody and control.

Subject to and without waiving the foregoing objections, Amylin responds as follows: To the extent such information exists in the files of the custodians agreed upon by the parties, Amylin refers Plaintiffs to documents previously produced in this litigation. Specifically, Amylin refers Plaintiffs to Exhibit D to Amylin's Responses and Objections to Plaintiffs' General Causation Interrogatories, which lists the custodians whose files have been produced, the custodians' job titles, and the Bates numbers at which documents from their files may be found. Plaintiffs can locate and identify documents responsive to this Request within these productions as readily as Amylin could.

ELI LILLY'S RESPONSE:

To the extent this request seeks FDA regulatory materials, Lilly objects to this request as misdirected to it, and refers Plaintiffs to Amylin, the regulatory approval holder for Byetta in the United States. Lilly further responds that to the extent documents potentially responsive to this request are contained in the custodial documents of individuals included within Lilly's custodial document production, they have been produced to Plaintiffs. Lilly's custodial document productions are identified by bates number in Appendix 3 to Lilly's Amended Objections and Responses to Plaintiffs' General Causation Requests to Produce. Lilly objects to this request as overbroad, unduly burdensome and not reasonably calculated to lead to admissible evidence to the extent it seeks documents from Lilly beyond those contained in Lilly's productions to date. Read literally it would require Lilly to interview or review documents from thousands of Lilly employees who have worked on Byetta. Lilly further objects to this request as exceeding the limited scope of preemption and general causation discovery defined in the Order Following August 14, 2014 Case Management Conference (Dkt. 567).

MERCK'S RESPONSE:

Merck objects to this Request to Produce as unduly burdensome, overly broad, irrelevant and as contrary to the limited approach to discovery ordered by the Court. Plaintiffs essentially ask Merck to search the custodial files of every employee who may have had any connection to JANUVIA® or JANUMET®. This is not the limited custodial approach agreed to by the parties and ordered by the Court. To the extent such documents exist in the files of the custodians agreed upon by the parties, those documents have already been produced.

NOVO'S RESPONSE:

NNI incorporates, as if fully set forth herein, the General Objections by reference. NNI further objects to this Request as vague and ambiguous as it fails to define key terms, including "consultant" or "employee." NNI further objects to this Request as overly broad, unduly burdensome and not reasonable to the extent it seeks information from any employee.

Without waiving or otherwise limiting the foregoing General and Specific Objections, NNI refers Plaintiffs to the custodial files of Michelle Thompson, Mary Ann McElligott, Alan Moses, and Jason Brett produced in searchable format produced within NOVO-0000001-3051319, which may include information responsive to this request.